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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,618	10/30/2003	Stina Gestrelius	S0002/7504D2	9884

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EXAMINER	
FORD, ALLISON M	
ART UNIT	**PAPER NUMBER**
1651	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/698,618	GESTRELIUS ET AL.	
	Examiner	Art Unit	
	Allison M. Ford	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-53,56 and 58-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-53,56 and 58-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response of 19 January 2007 has been received and placed into the application file. Claims 67-72 have been added; claims 50-53, 56, 58-60 and 62-65 have been amended; claims 1-49, 54, 55 and 57 are cancelled. Claims 50-53, 56 and 58-72 are pending in the current application, all of which have been considered on the merits. All arguments have been fully considered. Rejections/objections not repeated below have been withdrawn.

Priority

Applicant's claim for priority under 35 USC 121, as a divisional of application 10/156,300 (now US Patent 6,720,009) is acknowledged. US application 10/156,300 (USP 6,720,009) is a divisional of application 09/258,613 (now US Patent 6,503,539), which further claims priority to us provisional application 60/081,551, filed 13 April 1998. Support for the current claims is found in all parent applications, as such the effective filing date of the claims is considered to be 13 April 1998.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Amended claims 50-53, 56, 58 and 60-72 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating an inflammatory condition located in the oral cavity, does not reasonably provide enablement for treating any inflammatory condition not associated with the oral cavity. The specification does not enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

In response to the rejection of record, applicants have amended independent claim 50 to recite "treating a **local** inflammatory condition by topical application". It appears Applicants believe recitation of 'local inflammatory conditions' narrows the scope of the claim to exclude treatment of all inflammatory conditions in a mammalian body, including those which were exemplified as being non-enabled.

However, it is respectfully submitted that the instant amendment does not further limit or define the specific types of inflammatory conditions which can be treated successfully by application of the active enamel substance. A review of the specification fails to provide an explicit definition for the term 'local inflammatory conditions'; thus the term is given its general art accepted meaning: **4 :** *involving or affecting only a restricted part of the organism* (Retrieved from Merriam-Webster Online Dictionary, http://www.m-w.com/dictionary/local on 23 March 2007). Based on this definition, "local" inflammatory conditions still includes inflammatory conditions restricted to the lungs (asthma), pancreas (as in bouts of pancreatitis) or to the brain (encephalopathy); therefore, the current amendment fails to sufficiently narrow the scope of the instant claims to that which is supported and enabled by the instant disclosure.

Analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention without undue or unreasonable experimentation. See *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916). The key word is 'undue,' not experimentation.' " (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The factors to be considered in determining whether undue

experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

As amended, the method of independent claim 50 is drawn to a method of treating local inflammatory conditions by topical application [of an active enamel substance]; however, as discussed above, the term 'local inflammatory conditions' fails to narrow the scope of the claims; thus the claims still encompass treatment of any and all types of inflammation, in any area of the mammalian body, brought on by any cause. While the person of ordinary skill in the art, based on the teachings and knowledge generally available to the skilled artisan, as well as based on the teachings and experiments provided in the instant specification, would have a reasonable expectation of successfully treating inflammation in the oral cavity, caused by infection, oral surgery or other physical damage to the oral cavity, as well as symptoms associated with such inflammation by administering the active enamel substances disclosed in the present application, he or she would not have such an expectation for preventing inflammation in general or for treating inflammation in any other area of the mammalian body. Inflammation is a natural defense and repair mechanism of the body, it is required for healing wounds and destroying infections within the body. Inflammation is not limited to external wounds, but occurs frequently internally, for example, the body fights infection by invading pathogens (a desirable, and necessary response); or in the case of asthma, wherein the airways become inflamed and constrict in response to pathogenic or non-pathogenic triggers, such as allergens, temperature, or even stress (a non-desirable, but chronic and recurrent response).

The examples provided in the specification are limited to treatment of oral wounds caused by oral trauma (tooth extraction, oral ulcer, etc) or infection of such wounds; application of EMDOGAIN (active enamel substance) is reported to reduce the incidence of inflammation resulting from infection (as

EMODGAIN is reported to inhibit microbial growth) as well as reducing swelling associated with suturing (as EMODGAIN is reported to hasten the healing process). Thus, while the active enamel substance has been shown reduce (treat) inflammation in oral wounds caused by either infection or physical trauma (e.g. surgery, suturing, etc), there is not sufficient evidence or teachings to support the claim that the active enamel substances of the instant invention can effectively prevent any and all inflammation or even treat (reduce) inflammation not associated with the oral cavity. The specification does not provide teachings or guidance on how the active enamel substance can be delivered internally to treat inflammatory conditions present inside the body (i.e. inflammation of bronchial tubes during asthma attacks, inflammation of the pancreas during bouts of pancreatitis, inflammation of the brain caused by encephalopathy) which would be included in the scope of treating all inflammatory conditions in a mammalian body.

While lack of working embodiments that sufficiently cover the entire scope of the claim cannot be a sole factor in determining enablement, the absence of substantial evidence, in light of the unpredictable nature of the art and the direction applicants present, provides additional weight to the lack of enablement in consideration of the *Wands* factors as a whole. Thus one of ordinary skill in the art would not have a reasonable expectation of successfully preventing any and all inflammations, nor a reasonable expectation of successfully treating inflammations except those present in the oral cavity by performing the claimed method.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 50-53, 56 and 58-72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preamble of claim 50, as amended, now recites "A method for treating a local inflammatory condition by topical application;" the method as claimed involves "administering to a mammal in need thereof a therapeutically effective amount of an active enamel substance.". The language of the claim is current confusing because it is not clear if the topical application is to be of the active enamel substance, or if the active enamel substance is merely administered via any suitable route, and some other element or composition is topically applied. Correction is required.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leon B Lankford, Jr
Primary Examiner
Art Unit 1651